REMARKS

The withdrawal of the rejection of claims 1-3, 5, 12-15 and 21-26 under 35 U.S.C.§102(b) and the rejection of claims 4 and 6 under 35 U.S.C.§103(a) has been noted.

Claims 1-3. 7-17, 21-26 and 33 were rejected under 35 U.S.C.§103(a) as being unpatentable over Shah et al. (Shah) in view of Conte.

Reconsideration is requested.

Claim 1 has been amended by specifying that there is a "first segment" rather than a "first unitary segment" in order to adopt the language of original claim 1.In addition, claim 1 has been amended to delete the reference to a pharmacologically effective quantity of said drug or drugs present in said second segment and the reference to fewer milligrams of said drug or drugs relative to the excipients in each segment than. Claim 1 has also been amended to recite that the first segment has a score on its surface as pointed out in original claim 1 and in Fig.4a.

Nothing in the Shah patent discloses the concept of providing a segment in a divisible tablet where the first segment has either an undetectable amount of a drug or a pharmacologically ineffective amount of a drug.

Shah was applied as teaching divisible tablets for facilitating fractional dosing of medication where the sustained release characteristics were retained by each fractional dose. The Conte patent has been cited as disclosing a multilayer tablet where the first layer contains one or more drugs with an immediate or a controlled release formulation. The second layer contains a drug with a slow

release formulation and a third layer which has a low permeability barrier coating. The Examiner concluded that it would be obvious to one of ordinary skill in the art to make divisible tablets where the sustained release characteristics are retained as taught by Shah and to combine that tablet with the tablet disclosed by Conte.

The claims point out a tablet having a first segment where one face is contiguous with substantially identical first and second unitary segments that contain a drug or drugs where said first segment contains either an undetectable amount of a drug or a pharmacologically ineffective amount of drug. The Conte patent requires that the first and second contiguous segments must both contain drugs and that the third non-contiguous segment be the segment that has no drug. This is because in the Conte tablet, the third non-contiguous layer is a barrier layer which in order to function cannot be scored. The barrier cannot function as such if it is scored in the manner specified in the amended claim. The tablet defined by the amended claim of the present application can only be made by proceeding contrary to the Conte disclosure which is a hallmark of non-obviousness. It is not obvious to make a tablet that has a structure which can only be made by ignoring the teachings of the prior art.

Even when Conte is combined with Shah, there is no reason to modify Conte and have only one active segment contiguous with an inactive segment.

Claim 8 points out a tablet in which the first segment contains no more than 10% of the concentration of drug or drugs present in the first unitary segment and said second

unitary segment. This is not suggested by either the Shah or Conte patents when considered alone or in combination.

Claim 9 points out a tablet in which the first segment contains no more than a 2% concentration of the drug that is present in the first unitary segment and said second unitary segment. This is not suggested by either the Shah or Conte patents when considered alone or in combination.

Claim 10 points out a tablet as defined in which the first segment is derived from a granulation that does not contain a drug. This is not suggested by either the Shah or Conte patents when considered alone or in combination.

Claim 15 points out an embodiment having a vertical score aligned with the center of the space between said first unitary segment and said second unitary segment. This structure is not made obvious by the Shah or Conte patents.

In paragraph 8 of the Office Action, a rejection was entered based on Shah and Conte in view of Addicks et al. (Addicks). No claim was identified as being rejected by this combination of references but it is assumed that at least claims 17 and 18 are rejected over this combination.

Reconsideration is requested.

The Shah patent has been distinguished from amended claim 1 above and nothing in Conte or Addicks discloses the invention as defined by claims 17 and 18. Claims 17 and 18 depend on claim 1 which requires that a specific first segment be contiguous with the defined first and second unitary segments of the tablet. Addicks is only concerned with a two layer tablet that has no score and has no "layer where said first segment contains either an undetectable amount of a drug or a pharmacologically ineffective amount of

drug" as pointed out in amended claim 1. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 17 and 19 were rejected under 35 U.S.C.§ 103(a) as being unpatentable over Shah in view of Conte and further in view of Eberlin et al. (Eberlin).

Reconsideration is requested.

The Shah and the Conte patents have been distinguished from amended claim 1 above and nothing in Eberlin discloses the invention as defined by claims 17 and 19, which depend from amended claim 1. Claim 1 requires a specific first segment to be contiguous with the defined second segment of the tablet. Eberlin is concerned with a tablet that comprises digoxin and provides no information that makes the claimed tablet obvious. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 17 and 20 were rejected under 35 U.S.C.§ 103(a) as being unpatentable over Shah and Conte in view of Franz et al. (Franz).

Reconsideration is requested.

The Shah and Conte patents have been distinguished from amended claim 1 above and nothing in Franz discloses the invention as defined by amended claim 1 which requires a specific first segment to be contiguous with the defined second segment of the tablet. Claims 17 and 20 depend directly or indirectly from claim 1 and claims 17 and 18 are patentable for the reasons set forth above. Franz is only concerned with a tablet that comprises levothyroxine sodium. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 1-3, 7-26 and 33 have been provisionally rejected for double patenting over Serial No. 11/441,455 and have also been rejected over U.S. 7,329,418 and U.S. 7,318,935 for double patenting.

The provisional rejection of claims 1-3, 7-6 and 33 for double patenting has been noted since no claims have been allowed in either application, no action is required at this time.

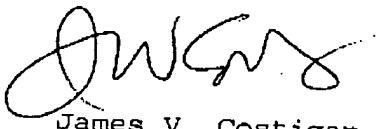
The claims of U.S. 7,329,418 (the '418 patent) do not make the claimed subject matter of the amended claims of the present application obvious because the claims of the '418 patent require a three layer structure and a particular height to width ratio. These structural elements do not make the claimed tablet obvious. This is particularly evident for claim 18, 19 and 20 which points out particular drugs that are not pointed out by the claims of the '418 patent.

The claims of U.S. 7,318,935 (the '935 patent) do not make the claimed subject matter of the amended claims of the present application obvious because the claims of the '935 patent also require a three layer structure and a particular height to width ratio. In addition, the subject matter of claims 18-20 of the present application are not made obvious by the claims of the '935 patent.

The applicants have disclosed a novel and unobvious invention and patent protection should be allowed.

An early and favorable action is earnestly solicited.

Respectfully submitted,



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